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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/444,791	05/19/1995	MANFRED BROCKHAUS	9191	5613
37500	7590	03/12/2007	EXAMINER	
AMGEN INC. LAW DEPARTMENT 1201 AMGEN COURT WEST SEATTLE, WA 98119			SCHWADRON, RONALD B	
			ART UNIT	PAPER NUMBER
			1644	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

08/444,791

Applicant(s)

BROCKHAUS ET AL.

Examiner

Ron Schwadron, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 125,127-130,132-138,140-145,147-149 and 155-212 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 204-207,209-211 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 07/580013.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 125,127-130,132-138,140-145,147-149,155-203,208 and 212.

1. As per the Office Action mailed 7/15/02, paragraph 1, the species under consideration is DNA encoding the 55 kD TNFBP and DNA encoding IgG3. Regarding applicants comments about how long the instant application has been pending, claims reading on the second species (eg. DNA encoding 75 kD receptor fusion protein) were not even present in the instant application until the amendment filed 8/31/2000. Regarding applicants comments about searching the other species, the searching of the other species would place a large and serious burden upon the Examiner. The two receptors are structurally unrelated and involve two gigantic separate sets of unrelated prior art. In fact, the searching and examination of the 75 kD would be equivalent to examining an entirely new unrelated patent application.

2. Claims 125,127-130,132-138,140-145,147-149,155-203,208 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the filed replies.

3. As per the Office Action mailed 9/23/03, paragraph 2, the elected invention is a polynucleotide/host cell/vector.

4. Claim 212 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the filed replies.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 204-207, 209-211 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", *Vas-Cath, Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the claimed inventions.

The only nucleic acid encoding a sequence comprising soluble portions of insoluble TNF binding proteins of a TNF receptor disclosed in the specification are those disclosed in Figures 1 and 4, wherein the sequences encode a 55kD or 75kD receptor. Regarding the claimed nucleic acid encoding a 55kD receptor, said claims would encompass DNA encoding alleles, variants and mutants of said 55kD receptor, wherein the only nucleic acid encoding a 55kD TNF receptor is that disclosed in the specification is that of Figure 1. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. In the instant case, the specification has disclosed a single nucleic acid encoding a 55kD TNF receptor with the nucleic acid sequence

disclosed in Figure 1. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

Regarding applicants comments, the claims under consideration that specify DNA encoding the 55kD receptor would encompass DNA encoding alleles, variants and mutants of said 55kD receptor, wherein the only nucleic acid encoding a 55kD TNF receptor disclosed in the specification is that disclosed in Figure 1. It is unpredictable as to what changes could be made to said molecule wherein the functional properties would be maintained. Furthermore, no mutants, variants or alleles of said molecule are disclosed in the specification. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species

encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. In addition, regarding applicants comments, the claims under consideration are not limited to a human TNF receptor and encompass a 55kD TNF receptor from any species. Regarding applicants comments, it appears that claims that specify DNA encoding the 55kD receptor would encompass DNA encoding alleles, variants and mutants of said 55kD receptor, wherein the only nucleic acid encoding a 55kD TNF receptor disclosed in the specification is that disclosed in Figure 1. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions.

The MPEP section 2163 (II A3.(a)(ii) states:

ii) For each claim drawn to a genus:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

*What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. **For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.** See, e.g., Eli Lilly. Description of a representative number of species does not*

require the description to be of such specificity that it would provide individual support for each species that the genus embraces. For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. Cf. In re Bell, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Baird, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, para. 1.

In the instant application a single a 55kD TNF receptor and nucleic acid encoding said receptor is disclosed in the specification in Figure 1. The claims encompass mutant, variants and alleles of said receptor that are not disclosed in the specification and wherein the sequence of said nucleic acids is not predictable. Attention is also directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 204-207, 209-211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schall et al. in view of Capon et al. (US Patent 5428130). Applicants arguments have been considered and deemed not persuasive.

Schall et al. teach the nucleic acid sequence encoding an insoluble (eg. membrane bound) TNF receptor (see Figure 1(a), wherein said sequence encodes a receptor that is about 55kD (eg. 415 amino acids, wherein the molecular weight would be 50,578, plus carbohydrate weight because the molecule is glycosylated, see page 368, first column, first complete paragraph)). Schall et al. teach the extracellular portion of said molecule (see page 362). The extracellular portion of the membrane bound molecule would be a soluble portion of said molecule. Schall et al. do not teach a nucleic acid encoding an Ig/soluble portion of a 55kD TNF receptor. Capon et al. teach DNA encoding Ig/ligand binding fusion proteins (see column 5). Capon et al. teach that the Ig/ligand binding fusion protein can contain the soluble portion of a cell surface receptor (eg. the receptor minus the transmembrane and cytoplasmic domains, see column 8, first complete paragraph). Capon et al. teach that the DNA encoding the Ig portion of the fusion protein can contain at least the hinge, CH2 and CH3 domains of the constant region of an Ig heavy chain or the Fc portion of the heavy chain (see column 10, second paragraph). Capon et al. teach vectors containing said DNA (see column 26). Capon teach the use of IgG-3 constant region in said fusion proteins (see claim 3). Capon et al. teach that the ligand binding portion of the Ig/ligand binding fusion protein can be derived from a wide variety of different known cell surface receptors (see column 7, third paragraph from bottom). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Schall et al. teach the nucleic acid sequence encoding an insoluble (eg. membrane bound) 55kD TNF receptor while Capon et al. teach DNA encoding soluble Ig/ligand binding fusion proteins wherein the ligand binding protein is a soluble portion derived from a cell surface receptor. One of ordinary skill in the art would have been motivated to do the aforementioned because Capon et al. teach that the ligand binding portion of the Ig/ligand binding fusion protein can be derived from a wide

variety of different known cell surface receptors (see column 7, third paragraph from bottom) and that said fusion proteins have a variety of a uses (see column 4).

Regarding applicants comments about priority document Swiss Patent application No. 746/90, *the claimed invention (eg. a DNA encoding a chimeric peptide)* is not disclosed in said application. Therefore, the claimed invention does not receive priority to said application regarding the application of prior art. The issue of the disclosure of said application versus the disclosure of Schall et al. is not germane to this issue. Regarding applicants comments about motivation to create the claimed invention, one of ordinary skill in the art would have been motivated to do have created the claimed invention because Capon et al. teach that the ligand binding portion of the Ig/ligand binding fusion protein can be derived from a wide variety of different known cell surface receptors (see column 7, third paragraph from bottom) and that said fusion proteins have a variety of a uses (see column 4), whilst Schall et al. teach the nucleic acid sequence encoding an insoluble (eg. membrane bound) 55kD TNF receptor.

Regarding applicants comments about the use of the phrase "obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention" in the instant rejection, said phrase is standard terminology used in 103 rejections as per the required *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 analysis. Regarding applicants comment, Capon et al. teach that:

"Typically, such fusions retain at least the functionally active hinge, CH2 and CH3 domains of the constant region of an immunoglobulin heavy chain." (see column 10, second paragraph). Furthermore, such a construct is recited in claim 12 of Capon et al. indicating that such a construct is a preferred fusion protein.

Regarding applicants various arguments related to nucleic acids encoding the 75 kD TNF receptor, said invention is not under consideration.

9. No claim is allowed.

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.129(a) and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.129(a). Accordingly, **THIS ACTION IS MADE**

FINAL even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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